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10/821,229	04/08/2004	Tara Ziolo	5490E-000365	9402
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HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303				
EXAMINER				
COTRONEO, STEVEN J				
ART UNIT		PAPER NUMBER		
3733				
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02/12/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/821,229

Applicant(s)

ZIOLO ET AL.

Examiner

STEVEN J. COTRONEO

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Response to Amendment

The declaration filed on 11/17/2009 under 37 CFR 1.131 has been considered but is ineffective to overcome the Duong reference.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Duong reference. The drawing submitted as exhibit A of the declaration do not show the relationship between the fixation hole of the plate and the annular member making exhibit A insufficient to show " wherein in the unexpanded position the fastener shaft and the annular member can rotate freely about the axis of the fastener shaft and collectively seat in the fixation hole at various angles relative to the fixation plate, and wherein in the expanded position the fastener shaft and annular member are prevented from backing out of the fixation hole" in claim 1 and similar limitations in claims 58 and 65.

The rejection based on Duong stands.

Claim Rejections - 35 USC § 102

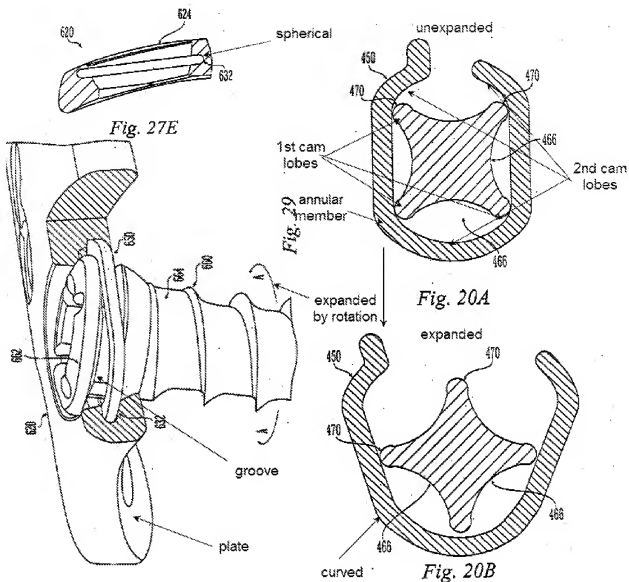
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 47-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Duong et al. (US 2005/0049593).

Duong et al. a bone fixation apparatus (see figures 20A, 20B and 29 below) having a bone fixation plate (fig 29) having a fixation hole and a fastener shaft passing through the fixation hole (fig 29). The fastener shaft has a longitudinal axis, and a first portion having an outer surface defining a first cam (fig 20) and a second bone-engaging portion. An annular member is received in the fixation hole (fig 29). The annular member circumferentially surrounding the first portion of the fastener shaft and has an inner surface defining a second cam for cooperating with the first cam to selectively expand the annular member in a radial direction from an unexpanded position to an expanded position Fig 20). The unexpanded position the fastener shaft and the annular member can rotate freely about the axis of the fastener shaft and collectively seat in the fixation hole at various angles relative to the fixation plate (fig 29), and in the expanded position the fastener shaft and annular member are prevented from backing out of the fixation hole. The unexpanded position (fig 20A) the cams provide a semi-constrained mode and in the expanded position (fig 20B) the cams provide a constrained mode. The annular member has a curved outer surface (fig 20). The fastener shaft has a circumferential groove (see fig 29 below) coupling the annular member for relative articulation (fig 29). The expanded position and unexpanded position is selective by rotation of the fastener shaft (fig 20A to 20B). The fixation hole is curved and has a spherical shape (fig 27, 632). The first and second cams have three continuous curves (see fig 20 below lobes are connected in a continuous manner).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

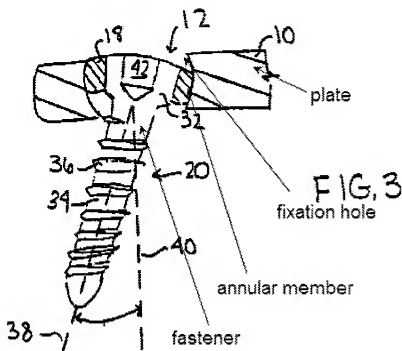
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47-66 rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US 2001/0014807) in view of Nielson (US 3,515,418).

Wagner et al. discloses a bone fixation apparatus (see fig 3 below) comprising: a bone fixation plate (fig 3, 10) having a fixation hole (fig 3, 12); a fastener shaft (fig 3, 20) passing through the fixation hole, the fastener shaft having a longitudinal axis, the fastener shaft including a head portion (fig 3, 32) and a bone-engaging portion; and an annular member (fig 3, 18) received in the fixation hole, the annular member circumferentially surrounding the first portion of the fastener shaft, wherein in an unexpanded position the fastener shaft and the annular member can rotate freely about the axis of the fastener shaft and collectively seat in the fixation hole at various angles relative to the fixation plate, and wherein in an expanded position the fastener shaft and annular member are prevented from backing out of the fixation hole (paragraph 59). The apparatus has a semi-constrained mode wherein the annular member is free to move in the plate and a constrained mode where the annular member is fixed (paragraph 59, "ring to expand such that the orientation of the bone screw relative to the plate is fixed."). The annular member has an outer surface and the fixation plate has an inner surface that is spherical (fig 3 and paragraph 46, "ball and socket joint"). The fixation plate is used for the vertebrae (title). The annular member has an expanded position that allows the annular member to rotate within the fixation hole (paragraph 49) and an expanded position that fixes the fastener to the hole (paragraph 59).

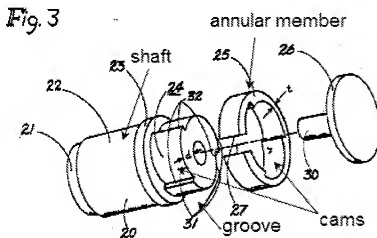
Wagner et al. discloses the claimed invention with the annular member being expanded by a threaded engagement between the annular member and the fastener

head. Wagner et al does not disclose the mechanism of expansion wherein the fastener shaft includes a first portion having an outer surface defining a first cam, and the annular member having an inner surface defining a second cam for cooperating with the first cam to selectively expand the annular member in a radial direction from an unexpanded position to an expanded position.



Nielson discloses the mechanism (see fig 3 below) wherein a shaft (fig 3, 20) includes a first portion (fig 3, 24) having an outer surface defining a first cam (fig 3, 31), and the annular member (fig 3, 25) having an inner surface defining a second cam (see fig 3 below) for cooperating with the first cam to selectively expand the annular member in a radial direction from an unexpanded position to an expanded position (col. 4, ll. 10-19). The cams have three continuous lobes (fig 3 and col. 3, ll. 39-40, "three cam

surfaces, each constituting continuous curve surfaces"). The shaft defines a groove that the annular member is carried in (fig 3, between 25 and 26).



It would have been obvious at the time of the invention to one of ordinary skill in the art to substitute threaded expansion engagement of Wagner et al. with the cam mechanism in view of Nielson because threaded expansion and the expansion caused by a cam are mere functional equivalents, and because such a substitution of one for the other would have achieved the same predictable result of expanding the annular member to fix the shaft within the a hole.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733

